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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/038,504	01/03/2002	Daryl A. Emery	293.00020101	5492

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EXAMINER

MINNFIELD, NITA M

ART UNIT	PAPER NUMBER
1645	10

DATE MAILED: 07/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/038,504	EMERY ET AL.
	Examiner	Art Unit
	N. M. Minnifield	1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 18 June 2003.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-71 is/are pending in the application.

4a) Of the above claim(s) 1-29, 31-33 and 39-71 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 30 and 34-38 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) 1-29, 31-33 and 39-71 are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 03 January 2002 is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5, 7.

4) Interview Summary (PTO-413) Paper No(s) _____.

5) Notice of Informal Patent Application (PTO-152)

6) Other: _____

DETAILED ACTION

1. Applicant's election with traverse of Group V, claims 30-38 and species *Salmonella spp.*, in Paper No. 9 is acknowledged. The traversal is on the ground(s) that the inventions as claimed can be readily evaluated in one search without placing undue burden on the Examiner. This is not found persuasive because the restricted Groups have acquired a separate status in the art as a separate subject for inventive effect and require independent searches. The search for each of the above inventions is not co-extensive particularly with regard to the literature search. A reference, which would anticipate the invention of one group, would not necessarily anticipate or make obvious any of the other groups. Moreover, as to the question of burden of search, classification of subject matter is merely one indication of the burdensome nature of the search involved. The literature search, particularly relevant in this art, is not co-extensive and is much more important in evaluating the burden of search. Burden in examining materially different groups having materially different issues also exist.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 1-29, 31-33 and 39-71 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions and/or nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 9.

3. Applicants' amendment filed June 18, 2003 is acknowledged and has been entered. Claims 53, 61, 63, 64, 66, 68 and 70 have been amended.

4. Claims 30 and 34-38 are under examination in the presently pending application.
5. The figures/drawings filed January 3, 2002 have been accepted by the Draftsman.
6. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.
7. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (see for example p. 14 of the specification). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.
8. The information disclosure statement filed August 28, 2002 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

The Examiner will consider references that have not been initialed if a copy of the references is provided along with the response to this Office Action.

Art Unit: 1645

9. The disclosure is objected to because of the following informalities: misspelled word, “prostaglandin”; does Applicant mean “prostaglandin”? Appropriate correction is required.

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 30 and 34-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Emery et al WO 95/21627 in light of Lumsden et al (Am. J. Vet. Res., 1991, 52/11:1784-1787).

The claims are directed to a method for reducing fecal shedding of a microbe in an animal's intestinal tract, the method comprising administering to an animal (avian, bovine, caprine, porcine or ovine) a composition comprising at least two siderophore receptor proteins, SRPs, (MW of 60-100 kD) from a gram negative microbe, at least two porins (MW of 30-43 kD) from a gram-negative microbe, LPS at a concentration of no greater than 10.0 EU/ml and a pharmaceutically acceptable carrier.

Emery et al discloses a vaccine for immunizing poultry (i.e. avian) and other animals against infection by gram-negative bacteria and that the vaccine comprises isolated SRPs from gram-negative bacteria, isolated porins from gram-negative bacteria and a physiologically acceptable carrier (abstract; p. 2; p. 47;p. 7). Emery

et al discloses that the SRPs have a molecular weight of 72-96 kD (p. 3; pp. 8-10) Emery et al also discloses that the composition comprises isolated porins from gram-negative bacteria having a molecular weight of 34-38 kD (p. 14). Emery et al set forth various gram-negative bacteria suitable for use in obtaining SRPs (p. 17).

Lumsden et al is cited to show that animals vaccinated with vaccines comprising gram-negative bacteria (i.e. *Salmonella spp.*) shed *Salmonella* less frequently than nonvaccinated control animals (summary). The vaccine prevented fecal shedding of microbes (p. 1784).

The prior art of Emery et al appears to disclose the claimed method of administering the claimed composition (SRPs, porins and physiologically acceptable carrier) to an animal. Although the prior art is silent with regard to LPS to claim recites that the composition has a concentration no greater than 10 EU/ml, therefore a composition that has no LPS would meet that limitation. Further, with regard to the recitation of "for reducing fecal shedding of a microbe in an animal's intestinal tract", this is viewed as a recitation of the intended use. The recitation of intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). In light of Lumsden it would appear that the vaccine composition of Emery et al would be useful to reduce fecal shedding of a microbe.

Since the Patent Office does not have the facilities for examining and comparing applicants' methods with the methods of the prior art reference, the burden is upon applicants to show a distinction between the material structural and functional characteristics of the claimed methods and the methods of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. Claims 30 and 34-38 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of U.S.

Patent No. 5830479 in light of Lumsden et al or claims 1-16 of U.S. Patent No. 6027736 in light of Lumsden et al. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the application and patents claim and disclose compositions comprising at least two siderophore receptor proteins, SRPs, (MW of 60-100 kD) from a gram negative microbe, at least two porins (MW of 30-43 kD) from a gram-negative microbe and a pharmaceutically acceptable carrier for use in a method for immunizing an animal (avian, bovine, caprine, porcine or ovine).

Emery et al (for example 5830479) discloses a vaccine for immunizing poultry (i.e. avian) and other animals against infection by gram-negative bacteria and that the vaccine comprises isolated SRPs from gram-negative bacteria, isolated porins from gram-negative bacteria and a physiologically acceptable carrier (abstract; claims; col. 1; col. 11). Emery et al discloses that the SRPs have a molecular weight of 72-96 kD (col. 2; claims; col. 8). Emery et al also discloses that the composition comprises isolated porins from gram-negative bacteria having a molecular weight of 34-38 kD (col. 7; claims). Emery et al set forth various gram-negative bacteria suitable for use in obtaining SRPs (col. 9).

Lumsden et al is cited to show that animals vaccinated with vaccines comprising gram-negative bacteria (i.e. *Salmonella spp.*) shed *Salmonella* less frequently than nonvaccinated control animals (summary). The vaccine prevented fecal shedding of microbes (p. 1784).

The prior art of Emery et al appears to disclose the claimed method of administering the claimed composition (SRPs, porins and physiologically acceptable carrier) to an animal. Although the prior art is silent with regard to LPS to claim recites that the composition has a concentration no greater than 10 EU/ml,

therefore a composition that has no LPS would meet that limitation. Further, with regard to the recitation of "for reducing fecal shedding of a microbe in an animal's intestinal tract", this is viewed as a recitation of the intended use. The recitation of intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). In light of Lumsden it would appear that the vaccine composition of Emery et al would be useful to reduce fecal shedding of a microbe.

14. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Art Unit: 1645

15. Claims 30 and 34-38 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 30 and 34-38 of copending Application No. 20030036639. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

16. No claims are allowed.

17. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is 703-305-3394. The examiner can normally be reached on M-F (8:00-5:30) Second Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette R.F. Smith can be reached on 703-308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Application/Control Number: 10/038,504
Art Unit: 1645

Page 10

N M Minfield
Primary Examiner

Art Unit 1645

NMM

July 8, 2003